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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,683	04/16/2004	Jiri Bartl	SYN-0038A	8863

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EXAMINER	
JAISLE, CECILIA M	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/825,683	BARTL ET AL.	
	Examiner	Art Unit	
	Cecilia M. Jaisle	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4-16-04, 8-25-04 & 12-8-04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12-8-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Rejections Under 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-33 are rejected under 35 USC 103, over Kennis, et al., U.S. Pat. No. 4,804,663, patented Feb. 14, 1989 [hereinafter, Kennis], alone and further in view of François, et al., U.S. Pat. No. 5,453,425, patented Sept. 26, 1995 [hereinafter, François] and Oshlack, et al., EP1227798, published May 10, 2001 [hereinafter, Oshlack].

Kennis describes and claims 3-piperdinyl-substituted 1,2-benzisoxazoles, including risperidone, 3-[2-[4-(6-fluoro-1,1-benzioxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one, and its pharmaceutically acceptable acid addition salts, including the hydrochloride salt (col. 1, line 23-col. 2, line 55 and col. 7, line 57-col. 8, line 4, and claims 1-6, *inter alia*). Kennis describes and claims pharmaceutical compositions with effective amounts such as between about 0.01 – 4 mg/kg of body weight of the subject (col. 10, lines 27-40, and claims 7-12, *inter alia*) and the compositions may include a pharmaceutically acceptable excipient (col. 9, line 33-col. 10, line 11, and claims 7-12, *inter alia*). Kennis notes, "Acid addition salts of (I) due to their increased water solubility over the corresponding base form, are obviously

more suitable in the preparation of aqueous compositions" (col. 10, lines 7-11, *inter alia*). The salts are prepared by contacting risperidone with a therapeutically active non-toxic acid, such as hydrochloric (col. 7, line 57-col. 8, line 4, *inter alia*). Sorbitol is incorporated into a formulation (Example 11). Kennis describes and claims methods of treating mammalian psychotic disorders with risperidone salts (col. 9, line 11-col. 10, line 40, and claims 13-18, *inter alia*).

The instant claims differ from Kennis by reciting specific salt forms of risperidone, while Kennis teaches acid addition salts broadly. One of ordinary skill in the art would have been motivated to prepare specific salt forms of risperidone, because Kennis generically shows such salt forms, their method of preparation and their increased water solubility. The skilled artisan would have had a reasonable expectation that these salt forms would also exemplify the psychotropic properties described by Kennis for risperidone. Further regarding the obviousness of the present claims, the ordinary organic chemist would have the skill to form a risperidone monohydrochloride salt by selecting stoichiometric quantities of base and acid, to isolate and purify the crystalline salt, or to carry out the salt formation in a suitable solvent, such as water or ethanol, since Kennis mentions these solvents as compatible with risperidone (col., 9, line 33-col. 10, line 11, *inter alia*). With regard to the recitation by claim 3 of water solubility, Kennis suggests the inherent characteristics of water solubility (col. 10, lines 7-11, *inter alia*). In regard to claim 11, the x-ray diffraction pattern is a characteristic of the compound of claim 10. With regard to claims 12-14, they recite inherent characteristics of the crystalline form of claim 5. MPEP 2112.01. A chemical composition and its

properties are inseparable. *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Regarding claims 13, 14, 17, 18, 23, 24, 27 and 28, that recite the hemipentahydrate salts, see François (col.1, lines 62-65) teaching that the term "addition salts" comprises solvates and hydrates, as well as Oshlack (page 7 of Description View) teaching that hemipentahydrate is a known suitable pharmaceutically acceptable salt for oral administration. It would be well within the ordinary pharmaceutical chemist's skill to determine the appropriate dosage from Kennis' teachings. The skilled chemist or pharmacologist would be well motivated to prepare other forms of risperidone for their expected pharmaceutical use.

Obvious Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over claims 1-22 of copending Application No. 10, 825,684 by Gieling, et al., entitled to the filing date of a provisional application April 22, 2003 [hereinafter, Gieling], alone and further in view of Oshlack. Gieling claims certain salts of risperidone, a method of making them, pharmaceutical compositions and method for treating mammalian psychotic disorders using these risperidone salts. The claims of the present application, directed specifically to certain hydrochloride salts of risperidone, a method of making them, pharmaceutical compositions and method for treating mammalian psychotic disorders using these risperidone salts, overlap the claims of Gieling. The teachings of Oshlack have been discussed above and they are incorporated here as equally pertinent. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cecilia M. Jaisle, J.D. whose telephone number is 571-272-9931. The examiner can normally be reached on Monday through Friday; 8:30 am through 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cecilia Jaisle, J.D.

DEEPAK RAO
PRIMARY EXAMINER